K070904

510(k) Summary

ANTLIA II™ SUCTION PUMP SYSTEM

APR 13 2007

1. **Name/Address of Submitter:** **Innovative Therapies, Inc.**
   10948 Beaver Dam Road, Suite C
   Hunt Valley, MD 21030

2. **Contact Person:** **Dave Tumey**

3. **Date Summary Prepared:** **March 16, 2007**

4. **Name of Device:** **ANTLIA II™ Suction Pump System**

5. **Classification Name:** **Powered Suction Pump**
   21 CFR 878.4780
   Class II

6. **Predicate Device:** **Medela Invia™ Healing System, K061435**
   BlueSky Medical Versatile 1™ Wound Vacuum System, K052456

7. **Description of Device**

The ANTLIA II™ Suction Pump System, an AC-powered, portable suction device with battery back-up, provides localized negative pressure when used with the Aquarius II™ dressing to remove fluids and infectious materials from the wound to promote wound healing. It is intended for use on patients who would benefit from a suction device, particularly as the device may promote wound healing, including patients who would benefit from vacuum assisted drainage and removal of infectious material, irrigation fluids or other body fluids from wounds.

The system consists of a powered suction pump device with a built-in placement holder for a fluid collection canister, the Aquarius II ™ polyurethane foam dressing, and canister tubing with clamps and connectors, and two polyurethane drapes with adhesive.

8. **Indication for Use**

The ANTLIA II™ Suction Pump System is indicated for the application of suction (negative pressure) to wounds to promote wound healing and for the removal of fluids, including wound exudates, irrigation fluids, body fluids and infectious materials.

9. Technological Characteristics and Substantial Equivalence

The ANTLIA II™ Suction Pump Therapy Unit has the same technological characteristics as the predicate's powered suction pump. The individual dressing components consists of materials that are either identical or substantially equivalent to the predicate's dressing components.

10. Conclusion

The substantial equivalence for the ANTLIA II™ Suction Pump System is based on the same indications, intended use, and technological features of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 7 2009

Innovative Therapies, Inc.
% Mr. David Tumey
8-2 Metropolitan Court
Gaithersburg, Maryland 20878

Re: K070904
Trade/Device Name: ANTLIA II™ Suction Pump System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: II
Product Code: OMP
Dated: March 20, 2007
Received: April 2, 2007

Dear Mr. Tumey:

This letter corrects our substantially equivalent letter of April 13, 2007.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not

limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070904

Device Name: ANTLIA II™ Suction Pump System

Indications For Use:

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(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070904

Prescription Use ___v___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)